DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

November 13, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-05

Scott E. Luedtke, Owner/Vice President
Bateman Food Distributors
1615 North 2nd Street
Coeur d'Alene, Idaho 83814

WARNING LETTER

Dear Mr. Luedtke:

We inspected your firm located at 1615 North 2nd Street, Coeur d'Alene, Idaho, on September 25, 26 and 29, 2000, and found that you have a serious deviation from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). An FDA 483 form (copy enclosed) listing the deviation was presented to you at the conclusion of the inspection. This deviation, which was previously brought to your attention, causes your refrigerated, vacuum packaged, raw salmon and halibut to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviation is as follows:

1. You must have a HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for refrigerated, vacuum packaged, raw salmon and halibut to control the food safety hazard of *Clostridium botulinum*. It is your responsibility to establish adequate safety controls for this food safety hazard. Refrigeration alone is not a suitable barrier to control *Clostridium botulinum* without adequate temperature control (monitoring) from processor to consumer.

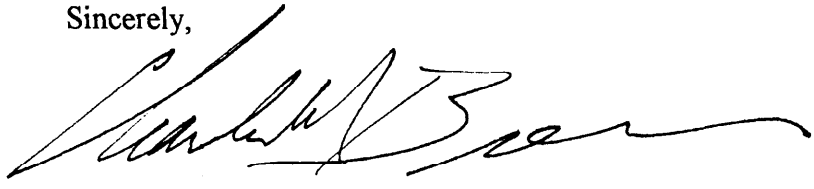
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation or other useful information that would assist us in evaluating your correction. If you cannot complete your correction before you respond, we expect that you will explain the reason for your delay and state when you will correct the deviation.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Ms. Althar at (425) 483-4940.

Sincerely,



Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ISDH with disclosure statement